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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/589,537	08/16/2006	Klaus Abraham-Fuchs	32860-001069/US	8506

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EXAMINER	
SEOH, MINNAH L	

ART UNIT	PAPER NUMBER
3686	

NOTIFICATION DATE	DELIVERY MODE
05/14/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/589,537	ABRAHAM-FUCHS ET AL.	
	Examiner	Art Unit	
	MINNAH SEOH	3686	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *04 February 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

1. This action is in reply to the Amendment/Response filed on 4 February 2010.
2. Claims 1-17 were amended.
3. Claims 1-17 are currently pending and have been examined.

Priority

4. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- Claim 1 recites "assigning a first search criterion." The first search criterion is then never used in the method step. In particular, the method determines a "measure for fulfilling the selection criterion for a patient associated with the patient data based on the second search criterion." Is the first search criterion also used to determine fulfillment of the selection criteria? Furthermore, the first search criterion is not clearly explained in the Specification. What is the

first search criterion? Is it merely one of multiple search criteria? It appears in the claim to be more than mere criteria since it is explicitly separate from the second criteria. Appropriate clarification and correction is required.

- Claim 1 recites "assigning a second search criterion to the selection criterion based on the medical study and distinct from the first search criterion." It is not clear what applicant's means by "distinct." The term "distinct" does not appear in the specification and it is not clearly apparent what is meant by the term. Are the two criterions used in different ways? Do they apply to different aspects of the study? At what point does a second criterion become "distinct" from the first criterion. For purposes of examination, distinct has been interpreted to mean different. Any two searches that are not identical are interpreted to meet the limitation of "distinct." Appropriate clarification and correction is required.
- Claim 6 recites "a probability value of 100% or 0% is determined based on other than the patient data." If the probability value is determined based on something other than patient data, what is it based on? There is no clear indication in the Specification of what factors are used to determine suitability other than patient data. Appropriate clarification and correction is required.
- All claims dependent from claim 1 are rejected for substantially the same reasons as above.

Claim Rejections - 35 USC § 101

7. In light of the amendment filed 4 February 2010, the rejection under USC 101 is withdrawn.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

9. Claims 1-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Boru et al. (US 2002/0077853).

CLAIM 1 –
As per claim 1, Boru et al. disclose a method comprising:

- assigning a first search criterion to the selection criterion based on the medical study *(**each search criterion in criteria array 511 having a non-zero value is compared, one at a time, with the corresponding search criterion** see **par. [0084] of Boru et al.**)*
- assigning a second search criterion to the selection criterion based on the medical study and distinct from the first search criterion *(**each search criterion in criteria array 511 having a non-zero value is compared, one at a time, with the corresponding search criterion** see **par. [0084] of Boru et al.**)*

- evaluating, using a processor, patient data stored in a database using the second criterion *(**each search criterion in criteria array 511 having a non-zero value is compared, one at a time, with the corresponding search criterion** see **par. [0084] of Boru et al.**)*
- determining, by the processor and based on the evaluation of the patient data, a measure for fulfilling the selection criterion for a patient associated with the patient data based on the second search criterion*(**search engine 100 generates a list 110 of the clinical trials (and optionally, corresponding abstracts) found in the database 101 that match the user's input data** see **par. [0080] of Boru et al.**)*
- selecting the patient as a potential participant for the medical study based on the determined measure

Though not explicitly stated in Boru et al., the final step of selecting a patient is implicit in the process of Boru et al. since Boru et al. discloses a method of providing a list of eligible clinical trials.

CLAIM 2 –
Boru et al. disclose the method of claim 1 above. Boru et al. further disclose:

- wherein the second search criterion is assigned to the selection criterion in accordance with known medical correlations *(**if abnormal liver function as indicated by bilirubin count...results in a patient being excluded from a***

clinical trial, these blood chemistry indicators are considered to be exclusionary criteria *see* ***par. [0028] of Boru et al.****)*

CLAIM 3, 8 –
Boru et al. disclose the method of claim 1 above. Boru et al. further disclose:

- wherein the second search criterion is assigned to the selection criterion in accordance with medical terms associated with the medical study*(****if abnormal liver function as indicated by bilirubin count...results in a patient being excluded from a clinical trial, these blood chemistry indicators are considered to be exclusionary criteria*** *see* ***par. [0028] of Boru et al.****)*
- the patient data is evaluated using a classification algorithm based on the second search criterion *(****each search criterion in criteria array 511 having a non-zero value is compared, one at a time, with the corresponding search criterion*** *see* ***par. [0084] of Boru et al.****)*

Claim 8 is rejected for substantially the same reasons as claim 3.

CLAIM 4, 9, 10, 11 –
Boru et al. disclose the method of claim 1 above. Boru et al. further disclose:

- the secondary criterion is assigned to the selection criterion in accordance with nonmedical correlations concerning the medical study *(****2. Location*** *see* ***Table 1 of Boru et al.****)*

Claim 9, 10, and 11 are rejected for substantially the same reasons as claim 4.

CLAIM 5 –
Boru et al. disclose the method of claim 1 above. Boru et al. further disclose:

- the measure for fulfilling the selection criteria is determined to be a probability value of 100% or 0%
- the patient selected as a potential participant is selected as an actual participant if the probability value for the patient is 100%,
- and the patient selected as a potential participant is not selected as an actual participant if the probability value for the patient is 0% ***(if abnormal liver function as indicated by bilirubin count...results in a patient being excluded from a clinical trial, these blood chemistry indicators are considered to be exclusionary criteria*** *see* ***par. [0028] of Boru et al.)***

Though not explicitly stated in Boru et al., the step of assigning a value of 0% or 100% to a potential participant is implicit. By assigning 0% or 100%, the method is essentially assigning a binary value of either "yes" or "no". Boru et al. will exclude a potential participant using exclusionary criteria. Therefore, Boru et al. explicitly teaches assigning no. Boru et al. does not specifically state assigning "yes", but implies the "yes" designation exists since patients are found to be acceptable for trials.

CLAIM 7, 15, 16, 17 –
Boru et al. disclose the method of claim 1 above. Boru et al. further disclose:

- wherein unstructured medical documents assigned to a patient are digitalized and stored in a text searchable format as patient data *(**at step 220, the clinical trial criteria in the initial criteria list 505 are 'normalized' (standardized) by assigning, to each of the criteria in the initial criteria list, a single, consistent search criterion name** see **par. [0040] of Boru et al.**)*

Note that the patient's data is entered and subsequently mapped to the criteria array *(see **par. [0083] of Boru et al.**)*. Since the criteria array is normalized, implicitly the patient's data has also been normalized in order to map to the criteria array.

Claim 15, 16, and 17 are rejected for substantially the same reasons as claim 7.

CLAIM 8 –
Boru et al. disclose the method of claim 2 above. Boru et al. further disclose:

- wherein the second search criterion is assigned to the selection criterion in accordance with medical terms associated with the medical study*(**if abnormal liver function as indicated by bilirubin count...results in a patient being excluded from a clinical trial, these blood chemistry indicators are considered to be exclusionary criteria** see **par. [0028] of Boru et al.**)*
- the patient data is evaluated using a classification algorithm based on the second search criterion *(**each search criterion in criteria array 511 having a non-zero value is compared, one at a time, with the corresponding search criterion** see **par. [0084] of Boru et al.**)*

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

11. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

12. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

13. Claims 6, 12, 13, and 14 rejected under 35 U.S.C. 103(a) as being unpatentable over Boru et al. in view of official notice.

CLAIM 6, 12, 13, 14 –
Boru et al. disclose the method of claim 1 above. Boru et al. further disclose:

- wherein a probability value except 100% and 0% is determined as the measure
- for the patient selected as a potential participant, a measure with a probability value of 100% or 0% is determined based on other than the patient data
- the patient selected as a potential participant is selected as an actual participant if the probability value for the patient is 100%
- the patient selected as a potential participant is not selected as an actual participant if the probability value for the patient is 0%

Since it is not stated in the specification how the probability value is being determined and the method of determining probability is interpreted by the examiner broadly, any method is acceptable using the data given. In Claim 6, the only thing known about how the probability value is determined is that it is not based on patient data. Therefore, the Examiner has interpreted the limitations in claim 6 broadly and has interpreted claim 6 to encompass a random number generator. Random number generators are well known in the art and would have been readily available to one of ordinary skill in the art at the time of the invention. Random selection of participants in clinical trials is also well known and it would have been obvious to one of ordinary skill in the art to use a random

number generator to select a patient as a participant based on a random number generator.

Claim 12, 13, and 14 are rejected for substantially the same reasons as claim 6.

Response to Arguments

14. Applicant's arguments filed 4 February 2010 have been fully considered but they are not persuasive.

15. With regards to Applicant's argument that Boru does not teach or fairly suggest "selecting the patient as a potential participant for the medical study based on the determined measure," this argument is unpersuasive. If a patient is selected as a potential participant for a medical study, the medical study is inherently being selected for the potential participant. If the claim language was amended to specify that the clinical trial was selecting the patient as a potential participant for the medical study, the inherency would no longer be clear. It is not stated in claim 1 who is doing the selecting so therefore the only limitation that is addressed is the selection itself. Furthermore, Applicant is arguing intended use which is nonfunctional in this case. The method steps in claim 1 are directed towards matching a patient with a clinical study. What happens after the matching occurs is not in any of the claims.

16. With regards to Applicant's argument that Boru's exclusionary criteria is different from the claimed first and second search criterion, this argument is unpersuasive. A first

and second criterion is not explicitly defined in the specification and it is not clear how the first and second criterions differ from simply two search terms. Without further explanation, they first and second criterions have been interpreted by the Examiner to be simply two search terms. Applicant admits in arguments that Boru has a list of exclusionary criteria, presumably containing more than one search term. Therefore, Boru has a first and second criteria.

Conclusion

17. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MINNAH SEOH whose telephone number is (571) 270-7778. The examiner can normally be reached on 9:00 AM - 4:00 PM Monday-Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jerry O'Connor can be reached on (571) 272-6787. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or (571) 272-1000.

/M. S./
Examiner, Art Unit 3686
May 3, 2010

/Gerald J. O'Connor/
Supervisory Patent Examiner
Group Art Unit 3686